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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,751	09/28/2001	Allan S. Myerson	14690.006US	2977

22870 7590 07/11/2003
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 07/11/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,751

Applicant(s)

MYERSON ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-23, 25-42 and 44 is/are rejected.
- 7) ☒ Claim(s) 8-10, 24, 43 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 and 09 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

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1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

There is no copendency between the instant application and application no. 09/348,200, which became abandoned on November 8, 2000.

The status of the applications referred to in the priority claim should be updated.

Correction is required.

The benefit claim filed on June 9, 2003 was not entered because the required reference was not timely filed within the time period set forth in 37 CFR 1.78(a)(2) or (a)(5). If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was

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due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Note that the requirement to petition applies when the relationship between parent applications is incorrectly stated, as well as when a priority claim is completely missing from an application. See the Notice by Deputy Commissioner Kunin dated February 24, 2003, at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/benefitclaims.pdf>.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-5, 11-21, and 25-39 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-88 of copending Application No. 10/222,506. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '506 application anticipate instant claims 1-4, 11-19, 25-30. With respect to instant claims 5, 20, and 39, while the '506 application does not claim a laser wavelength of 1064 nm, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal near infrared wavelengths for the claimed

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method of the '506 application, because the '506 application claims the step of selecting a wavelength and because it is prima facie obvious to determine and optimize all art-recognized result-effective variables. With respect to instant claim 21, while the '506 application does not claim a power between 0.1 and 10 GW/cm², it would have been obvious to one of ordinary skill in the art to determine all operable and optimal powers for the laser light of the claimed method of the '506 application, because the '506 application claims the step of selecting a power, and because it is prima facie obvious to determine and optimize all art-recognized result-effective variables.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-5, 11-21, and 25-39 are directed to an invention not patentably distinct from claims 1-88 of commonly assigned U.S. Patent Application 10/222,506. Specifically, see the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. Patent Application 10/222,506, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject

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matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

5. Claims 1, 3-7, 9, and 11-18 are directed to an invention not patentably distinct from claims 1-33 of commonly assigned copending Application No. 09/918,935. Specifically, the claims of the '935 application anticipate instant claims 1, 3, 4, 6, 7, 9, and 11-18. With respect to instant claim 5, while the '935 application does not claim a laser wavelength of 1064 nm, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal near infrared wavelengths for the claimed method of the '935 application, because the '935 application claims the step of selecting a wavelength and because it is prima facie obvious to determine and optimize all art-recognized result-effective variables.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 09/918,935, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to

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name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

6. The effective filing date of instant claims 1, 3, 4, 9-14, and 16-18 is deemed to be October 23, 2000, the filing date of parent application 09/694,404. Instant claims are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '404 parent application because the '404 parent application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

The effective filing date of instant claims 2, 5-8, 15, and 19-45 is deemed to be September 28, 2001, the filing date of the instant application. Instant claims 2, 5-8, 15, and 19-45 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/694,404 because the '404 parent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the specific aging time range of 1 hour to 200 hours, does not disclose the specific wavelength of 1064 nm, does not disclose light with linear, circular, or elliptical polarization, does not disclose the specific pulse rate range of between 1 and 100 pulses per second, and does not disclose the specific power range of between 0.1 and 10 GW/cm².

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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8. Claims 2, 5-7, 15, 19-23, 25-42, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Myerson (U.S. Publication No. 2003/0024470). Myerson teaches preparing supersaturated protein solutions by a combination of heating and cooling, aging the supersaturated protein solutions, and then treating the aged protein solutions with polarized laser light having a wavelength of 1064 nm and pulse rate of 10 pulses per second. The solvent can be water. Polarization can be linear or circular, the laser power can be 0.7 GW/cm^2 , and laser treatment time can range from 0.01 to 60 seconds. Aging can last for as little as 48 hours. See e.g., paragraphs 0040, 0046, 0058, 0059, and 0064.

9. Applicant's arguments filed June 9, 2003 have been fully considered but they are not persuasive.

The terminal disclaimers filed over U.S. Patent No. 6,426,406 and over U.S. Patent Application No. 09/918,935 have been approved.

Concerning the requirement to show common ownership at the time the invention was made set forth in paragraph 8 of the previous Office action and repeated in paragraph 4 above, this issue is not moot as long as there are claims conflicting between the two applications. A terminal disclaimer does not address this issue.

U.S. Patent Application Publication 2003/0101926, which is based upon U.S. Patent Application 10/222,506 applied above, is not applied against the instant claims under 35 U.S.C. 102(e) because it will be prior art under 35 U.S.C. 102(e) against the instant claims only to the extent that that its parent application 09/918,935 is prior art against the instant claims. Accordingly, any prior art rejection under 35 U.S.C. 102(e) rejection based upon U.S. Patent Application Publication 2003/0101926 would at best be duplicative of any prior art rejection

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based upon U.S. Patent Application Publication 2003/0024470, which published based upon parent application 09/918,935.

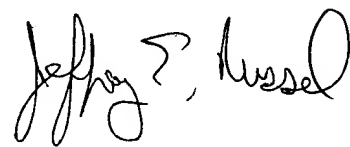
The anticipation rejection based upon Myerson (U.S. Patent Application Publication 2003/0024470) is maintained. Myerson '470 teaches the formation of crystals. See, e.g., the Title and paragraph 40. A crystal necessarily has a polymorph. Because Applicants' claims do not require that any particular crystal polymorph be produced (in the sentence bridging pages 16 and 17 of the response, the word "particular" has no support in the rejected claims), whatever crystal polymorph is produced by the process of Myerson '470 will meet Applicants' claimed requirement that a crystal polymorph be produced. Applicants argue that their invention is directed towards a method for preparing crystal polymorphs and not for nucleating protein solutions. However, it is noted that claim 1, step c; claim 19, step c; and claim 31, step d; of the instant application each recite nucleating solutions. Further, Applicants have provided no explanation as to how Myerson '470 can produce a crystal of a substance and not produce a crystal polymorph.

10. Claims 8-10, 24, 43, and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Russel" clearly distinguishable.

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 10, 2003